

**REMARKS****I. PRELIMINARY REMARKS**

Claims 45, 65, 66 and 69 have been amended. No claims have canceled. Claims 75- 96 have been added. Claims 45-48, 50-54, 65, 66, 68-71 and 73-96 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes that the Office Action indicated that claim 54 is directed to patentable subject matter. With respect to claim 66, applicant has assumed for the purposes of this response that the Examiner intended to object to claim 66 because it depended from a canceled claim. This typographical error has been corrected and, with respect to patentability, applicant respectfully submits that claim 66 is patentable for at least the same reasons as the independent claim from which it now depends.

**II. REJECTION UNDER 35 U.S.C. § 102****A. The Rejection**

Claims 45-48, 50-53, 65, 68-71, 73 and 74 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,336,182 to Lundquist ("the Lundquist '182 patent"). The rejection under 35 U.S.C. § 102 is respectfully traversed with respect to the extent that it is applicable to the claims as amended above. Reconsideration thereof is respectfully requested.

**B. The Applicable Legal Standards**

With respect to claim interpretation, the *en banc* Federal Circuit decision in *Phillips v. AWH Corp.*, 75 USPQ2d 1321, 1329, (Fed. Cir. 2005), indicated that "[t]he Patent and Trademark Office ("PTO") determines the scope of the claims in patent applications not

solely on the basis of the claim language, but upon giving the claims their broadest reasonable construction ‘in light of the specification as it would be interpreted by one of ordinary skill in the art.’” *Citing In re American Academy of Science Technology Center*, 70 USPQ2d 1827, (Fed. Cir. 2004).” In other words, the interpretation must be “consistent with the specification” and “consistent with the one that those skilled in the art would reach.” *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999).

Turning to patentability under 35 U.S.C. § 102, “[a] rejection for anticipation under section 102 requires that **each and every** limitation of the claimed invention be disclosed in a single prior art reference.” *In re Paulsen*, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (citations omitted).

Finally, some the claims in the present application include a means-plus-function element. The MPEP requires a **two-part analysis** of means-plus-function elements. **First**, “the application of a prior art reference to a means or step plus function limitation **requires** that the prior art element **perform the identical function** specified in the claim.” [MPEP § 2182, emphasis added.] **Second**, “**if a prior art reference teaches identity of function** to that specified in a claim, **then** under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.” [Id., emphasis added.]

### C. The Lundquist ‘182 Patent

The Lundquist ‘182 patent is directed to a steering mechanism that may be inserted into the lumen of a non-steerable device and used to steer the non-steerable device to the target location. [Column 3, lines 57-66.] In some implementations, the steering mechanism may be removed from the non-steerable device after the non-steerable device reaches the target location, while in others, the steerable device may be secured to the non-steerable device with adhesive (Figure 25). Referring to Figures 1-5, the steering mechanism 10 includes flexible shaft 30 with an internal coil spring 170, a steering wire 120 with a distal end 150 that is secured to a lead spring 230 by a weld 260, and a ferrule 190 mounted on

the coil spring 170 with slots 210 and 220 that receive the lead spring 230. The ferrule 190 may also be eliminated and the lead spring 230 mounted in the end of the coil spring 170. [Figure 36; and column 5, lines 34-40.]

#### D. Discussion Concerning Claims 45 and 46

Independent claim 45 calls for a combination of elements including, *inter alia*, “an elongate body defining a proximal portion and a distal portion,” “a steering wire having a distal portion,” “an **anchoring member** associated with the distal portion of the elongate body, **configured such that it does not obstruct the aperture** in the distal portion of the elongate body, and **directly secured to the steering wire**” and “means, directly connected to the anchoring member, for preventing compression of the elongate body distal portion during bending of the elongate body distal portion.” The combination defined by claim 46 includes, *inter alia*, the elements recited in claim 45.

The Lundquist ‘182 patent fails to teach or suggest a number of aspects of the claimed combinations. For example, the Office Action appears to have taken the position that the tip member at the distal end of the shaft 30 corresponds to the claimed “anchoring member.” [Office Action at page 2.] In contrast to the claimed combination, however, the Lundquist distal tip completely obstructs the aperture at the distal end of the shaft 30. Moreover, in those instances where the steering mechanism 10 is inserted into a non-steerable device, the steering mechanism 10 (including the distal tip member) will obstruct, in whole or in part, the lumen at the end of the non-steerable device.

As the cited reference fails to teach or suggest each and every element of the combination recited in independent claim 45, applicant respectfully submits that the rejection of claims 45 and 46 under 35 U.S.C. § 102 should be withdrawn.

#### E. Discussion Concerning Claims 47, 48, 50, 51 and 53

Independent claim 47 calls for a combination of elements including, *inter alia*, “an elongate body defining a proximal portion” and “a stiffening member associated with the

distal portion of the elongate body.” The respective combinations defined by claims 48, 50, 51 and 53 include, *inter alia*, the elements recited in claim 47.

The Lundquist ‘182 patent fails to teach or suggest a number of aspects of the claimed combinations. For example, the Office Action appears to have taken the position that the weld 260, which connects the steering wire 120 to the lead spring 230, corresponds to the claimed “stiffening member” because the weld 260 is “stiffer than the flexible catheter in which it resides.” [Office Action at page 4.] While it may be true that what appears to be a spot weld is stiffer than the Lundquist shaft 30, applicant respectfully submits that there is no reasonable interpretation of the phrase “stiffening member” that would read on a spot weld. The present specification indicates that a “stiffening member” is something that “prevents compression (or “buckling”) of the elongate body distal portion 24 during bending.” [Spec. at page 12, lines 16-26.] The Lundquist weld 260 does not prevent the compression or buckling of anything. Nor is the physical configuration of a spot weld even remotely related to the physical configurations of the exemplary stiffening members described in the present specification.

As the cited reference fails to teach or suggest each and every element of the combination recited in independent claim 47, applicant respectfully submits that the rejection of claims 47, 48, 50, 51 and 53 under 35 U.S.C. § 102 should be withdrawn.

#### F. Discussion Concerning Claim 52

Independent claim 52 calls for a combination of elements including, *inter alia*, “an elongate body,” “a steering wire having a distal portion operably connected to the distal portion of the elongate body,” “a stiffening member associated with the distal portion of the elongate body” and “a substantially c-shaped anti-tear device with a slot associated with the stiffening member.” Claim 52 also indicates that “a portion of the steering wire is positioned within the slot.”

The Lundquist ‘182 patent fails to teach or suggest the claimed combination. For example, the Office Action appears to have taken the position that the Lundquist steering wire 120 corresponds to the claimed “steering wire” and the Lundquist ferrule 190, which

includes slots 210 and 220, corresponds to the claimed “anti-tear device.” [Office Action at pages 5 and 6.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, no portion of the steering wire 120 is positioned within the purported anti-tear device “slot” (i.e. one of the ferrule slots 210 and 220). Instead, and as is clearly illustrated and described in the Lundquist patent, the broad portion 250 of lead spring 230 is located within the slots 210 and 220. [Figures 2, 3 and 5; and column 5, lines 16-26.]

As the cited reference fails to teach or suggest each and every element of the combination recited in independent claim 52, applicant respectfully submits that the rejection of claim 52 under 35 U.S.C. § 102 should be withdrawn.

#### **G. Discussion Concerning Claim 65**

Independent claim 68 calls for a combination of elements including, *inter alia*, “an elongate body defining a proximal portion and a distal portion and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion” and “a steering wire having a distal portion that is located within the elongate body wall between the inner surface and the outer surface and is operably connected to the distal portion of the elongate body.”

The Lundquist ‘182 patent fails to teach or suggest the claimed combination. For example, the Office Action appears to have taken the position that the Lundquist shaft 30 corresponds to the claimed “elongate body” and the Lundquist steering wire 120 corresponds to the claimed “steering wire.” [Office Action at page 6.] In contrast to the claimed combination, however, the steering wire 120 is not located within the wall of the shaft 30 between the inner and outer surfaces. The steering wire 120 is, instead, located within the central lumen of the shaft 30.

As the cited reference fails to teach or suggest each and every element of the combination recited in independent claim 65, applicant respectfully submits that the rejection of claim 65 under 35 U.S.C. § 102 should be withdrawn.

#### H. Discussion Concerning Claim 68

Independent claim 68 calls for a combination of elements including, *inter alia*, “an elongate body,” “a stiffening member associated with the distal portion of the elongate body” and “anti-tear means, associated with the stiffening member, for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body.”

The Lundquist ‘182 patent fails to teach or suggest the claimed combination. For example, the Office Action appears to have taken the position that the Lundquist weld 260, which connects the steering wire 120 to the lead spring 230, corresponds to the claimed “stiffening member” because the weld 260 is “stiffer than the flexible catheter in which it resides,” and the Lundquist ferrule 190 corresponds to the claimed “anti-tear means.” [Office Action at pages 7-8.] Applicant respectfully submits that such an interpretation is unreasonable because the ferrule does not perform the function of “increasing the elongate body surface area over which the force is applied when the [weld 260] is bent to prevent the [weld 260] from tearing through the elongate body.”

As the cited reference fails to teach or suggest each and every element of the combination recited in independent claim 68, applicant respectfully submits that the rejection of claim 68 under 35 U.S.C. § 102 should be withdrawn.

#### I. Discussion Concerning Claims 69, 73 and 74

Independent claim 69 calls for a combination of elements including, *inter alia*, “an elongate body defining a proximal portion and a distal portion,” “a steering wire having a distal portion,” “a steering wire having a distal portion,” “an anchoring member,” “a stiffening member associated with the distal portion of the elongate body” and “a substantially tubular member **directly secured** to the stiffening member.” The respective combinations defined by claims 73 and 74 include, *inter alia*, the elements recited in claim 69.

The Lundquist '182 patent fails to teach or suggest the claimed combination. For example, the Office Action appears to have taken the position that the Lundquist weld 260, which connects the steering wire 120 to the lead spring 230, corresponds to the claimed "stiffening member" because the weld 260 is "stiffer than the flexible catheter in which it resides," and the Lundquist ferrule 190 corresponds to the claimed "tubular member." [Office Action at page 9.] Applicant respectfully submits that the Office Action's interpretation of "stiffening member" is improper for the reasons presented in Section II-E above. In addition, the purported "tubular member" (i.e. the ferrule 190") is not directly secured to the purported "stiffening member" (i.e. the weld 260).

As the cited reference fails to teach or suggest each and every element of the combination recited in independent claim 69, applicant respectfully submits that the rejection of claims 69, 73 and 74 under 35 U.S.C. § 102 should be withdrawn.

#### **J. Discussion Concerning Claims 70 and 71**

Independent claims 70 and 71 call for respective combinations of elements including, *inter alia*, "an elongate body defining a proximal portion and a distal portion," "a steering wire having a distal portion," "an anchoring member associated with the distal portion of the elongate body and directly secured to the steering wire."

The Lundquist '182 patent fails to teach or suggest the claimed combinations. For example, the Office Action appears to have taken the position that the steering wire 120 that is part the device illustrated in Figure 1-6 of the Lundquist patent corresponds to the claimed "steering wire," that the welds 390, which connect the steering wires 360 and 370 to the lead spring 350 in the device illustrated in Figure 25-30 of the Lundquist patent correspond to the claimed "anchoring member," and that the weld 260, which connects the steering wire 120 to the lead spring 230 in the device illustrated in Figure 1-6 of the Lundquist patent, corresponds to the claimed "stiffening member." [Office Action at pages 10-12.] Notwithstanding the impropriety of reading the claimed "anchoring member" and "stiffening member" on a collection of spot welds, the rejection under Section 102 is improper because it mixes and match the elements of the device illustrated in Figures 1-6

with the elements of the device illustrated in Figures 25-30. Such mixing and matching, absent an explicit teaching to do so, is impermissible in a rejection under 35 U.S.C. § 102.<sup>1</sup>

As the cited reference fails to teach or suggest each and every element of the respective combinations recited in independent claims 70 and 71, applicant respectfully submits that the rejection of claims 70 and 71 under 35 U.S.C. § 102 should be withdrawn.

### III. NEWLY PRESENTED CLAIMS 75-96

Newly presented claims 75-79 depend from independent claim 45 and, accordingly, are patentable for at least the same reasons as claim 45.

Newly presented claims 80-82 depend from independent claim 47 and, accordingly, are patentable for at least the same reasons as claim 47.

Newly presented claims 83-86 depend from independent claim 52 and, accordingly, are patentable for at least the same reasons as claim 52.

Newly presented claims 87-88 depend from independent claim 65 and, accordingly, are patentable for at least the same reasons as claim 65.

Newly presented claims 89-91 depend from independent claim 68 and, accordingly, are patentable for at least the same reasons as claim 68.

Newly presented claim 92 depends from independent claim 69 and, accordingly, are patentable for at least the same reasons as claim 69.

Newly presented claims 93-94 depend from independent claim 70 and, accordingly, are patentable for at least the same reasons as claim 70.

Newly presented claims 95-96 depend from independent claim 71 and, accordingly, are patentable for at least the same reasons as claim 71.

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<sup>1</sup> To anticipate, every element and limitation of the claimed invention must be found in a single prior reference, arranged as in the claim. *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 58 USPQ2d 1286 (Fed. Cir. 2001), citing *C.R. Bard, Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225, 1229-30 (Fed. Cir. 1998).

**IV. CLOSING REMARKS**

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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